Supreme Court, U.S.
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No. 95-2018

IN THE

Supreme Court of the United States

October Term, 1995

HOWMEDICA INC.,

Petitioner,

v.

MARILYN HAUDRICH, as Executor and Sole Legatee of Donald Haudrich, Deceased,

Respondent.

On Petition for Writ of Certiorari to the Supreme Court of the State of Illinois

SUPPLEMENTAL BRIEF FOR PETITIONER

Steven C. Kany
Louis B. Bernstein
PFIZER INC.
235 E. 42nd Street
New York, NY 10017
(212) 573-2323

James V. O'Brien
Thomas L. Caradonna
LEWIS, RICE & FINGERSH, L.C.
500 N. Broadway, Ste. 2000
St. Louis, MO 63102
(314) 444-7600

Barry Levenstam
Counsel of Record

Stephanie A. Scharf
Matthew M. Neumeier
JENNER & BLOCK
One IBM Plaza
Chicago, IL 60611
(312) 222-9350
Counsel for Petitioner

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Petitioner Howmedica Inc. ("Howmedica") hereby submits this supplemental brief in light of this Court's decision in *Medtronic, Inc. v. Lohr*, 64 U.S.L.W. 4625 (U.S. June 26, 1996).

This Petition now presents directly a question that was subsumed in the question presented in the Petition but not resolved by the Court's narrow decision in *Medtronic*: whether the Medical Device Amendments of 1976 (the "MDA"), 21 U.S.C. § 360 *et seq.* (1994), pre-empt a state-law action directed at a medical device that actually passed the Food & Drug Administration's ("FDA") scrutiny, particularly where the action challenges design or manufacturing features of the device that obtained specific FDA approval.

ARGUMENT

In *Medtronic*, this Court addressed the question whether state-law tort claims involving the design, manufacture, and labeling of a medical device that had not completed the "premarket approval" or "PMA" process are pre-empted by 21 U.S.C. § 360k(a) (1994) (App. 58a). The pacemaker at issue was a "Class III" device that was permitted to be marketed pursuant to the "§ 501(k) process," following a determination by the FDA that the device was "substantially equivalent" to similar devices. The Court held that design defect claims were not pre-empted because the FDA never approved the design of this particular device, see 64 U.S.L.W. at 4631-32 (opinion of STEVENS, J.); *id.* at 4637 (O'CONNOR, J., concurring in part and dissenting in part), and that claims based on negligent manufacturing and labeling also were not pre-empted because the device was subject only to FDA regulations on manufacturing and labeling of general applicability, and not specific to this particular device. *Id.* at 4633-34 (Opinion of STEVENS, J.).

This case, however, involves a device that has successfully completed the FDA's rigorous PMA "gauntlet," after first being authorized for use as an experimental device in a clinical investigation pursuant to the FDA's Investigational Device Exemption ("IDE") process. See 21 U.S.C. § 360j(g) (1994) (App. 54a-58a); 21 C.F.R. Pt. 812 (1995). Thus, this case presents an issue of national importance that has not been resolved by *Medtronic* regarding the nature and scope of pre-emption for Class III devices that have been fully reviewed and approved by the FDA, and the subject matter jurisdiction of state courts over such claims generally.

A. The IDE-Approved and PMA-Approved Device At Issue And Plaintiff's Claims of Design Defect

The device at issue in this case is known as the P.C.A.® Total Knee System. The regulatory history of this particular device is set forth in detail in *Dawson v. Howmedica, Inc.*, 886 F. Supp. 1402 (E. D. Tenn. 1995); a summary follows.

When first introduced in 1981, the FDA classified the device as a Class II device labeled for use only with bone cement, and cleared it by the § 501(k) process. Later in 1981, Howmedica sought FDA authorization to conduct a clinical study and investigation of the use of the device *without* bone cement. The FDA granted approval of the IDE and authorized a clinical investigation early in 1982. The device that was implanted in plaintiff was utilized during the period in which the IDE clinical investigation was underway.

When the clinical investigation was completed, Howmedica submitted a PMA application for the device to be labeled for use without bone cement in 1984. 53 Fed. Reg. 51,007 (Dec. 12, 1988) (App. 64a-66a). After considering the application, including data on the safety and effectiveness of the device, the FDA granted premarket approval in 1988. *Id.* As a result, the P.C.A.® Total Knee System is now classified as a Class III device, having completed two full rounds of intense FDA scrutiny--first pursuant to the IDE process, and subsequently pursuant to the PMA process.

Notwithstanding the FDA's critical role in authorizing the development, marketing and use of this device, following a satisfactory demonstration of its safety and effectiveness, plaintiff's decedent was permitted to bring an action in Illinois state court complaining that the device was defective and unreasonably dangerous in its design. At trial, the expert testimony focused on two design criteria. First, plaintiff's experts contended that a certain polyethylene plastic tibial insert component was "too thin," *i.e.*, being 7 millimeters in thickness rather than 9 millimeters (one of a range of other thicknesses also approved by the FDA) (App. 4a-7a, 40a-41a, 44a). They also criticized the heat-polishing technique utilized to fabricate this component (App. 6a-7a, 39a-41a). Based on this testimony, the trial

court held that the device was defective and unreasonably dangerous and awarded $1,686,989.70 in damages.

B. Federal Pre-emption for IDE-Approved and PMA-Approved Devices

Congress unquestionably was motivated by a concern for protecting public health and safety when enacting the MDA. At the same time, however, Congress recognized the need to encourage innovation in medical technology and to protect against disparate state-law requirements that might stifle such innovation, particularly with regard to new and experimental devices like the one at issue here. See, e.g., *Medtronic*, 64 U.S.L.W. 4631, n.12 (Opinion of STEVENS, J.) (noting the "[s]pecial statutory exemptions" for investigative, experimental devices); H.R. Rep. No. 853, 94th Cong., 2d Sess. 12 (1976).

The MDA, pursuant to the IDE process, exempts investigational devices from a number of requirements for devices, including the requirements relating to a demonstration of the safety and effectiveness of the device pursuant to the PMA process for Class III devices. See 21 C.F.R. § 812.1(a) (1995). These exemptions are explicitly intended to encourage innovation and experimentation in cases where extraordinary medical remedies are warranted. See 21 U.S.C. § 360j(g) (1994) (App. 54a-58a). To receive approval under the IDE process, the manufacturer must submit a detailed application describing the device and setting forth a plan for studying its use in human subjects during the period of experimentation. See 21 C.F.R.§ 813.20 (1995). The recipients of a device who are part of the IDE study are informed of the device's investigational status and the risks involved. See 21 U.S.C. § 360j(g)(3)(D) (1994) (App. 56a-57a); 21 C.F.R. § 813.66(a)(6) (1995). During the study period, an institutional review committee monitors the clinical investigations instituted pursuant to the IDE process. See 21 C.F.R. § 813.65 (1995). The FDA ultimately will not approve an IDE absent a determination that the device has sufficient promise of being proved safe and effective, through the clinical investigation, to justify the risk of its experimental use in human beings. *Slater v. Optical Radiation Corp.*, 961 F.2d 1330, 1333 (7th

Cir.), *cert. denied*, 506 U.S. 917, 113 S. Ct. 327, 121 L. Ed. 2d 246 (1992).

Howmedica fully complied with the requirements of the IDE process when obtaining FDA approval of its application. See *Dawson*, 886 F. Supp. at 1405 (noting that the purpose of Howmedica's IDE investigation "was to determine the safety and effectiveness of the [device] in patients undergoing non-cemented total knee joint replacement"). Included within the information required to be submitted prior to approval of the IDE was detailed information on the manufacturing, quality control, and packing and labeling procedures concerning this specific device, as well as information concerning the protocol for the clinical study and the proposed investigators. *Id.* at 1405-07. Following FDA approval, the IDE remained in effect until Howmedica subsequently obtained FDA approval as a Class III device pursuant to the PMA process.

The PMA process similarly requires manufacturers to submit to the FDA samples of the device and its proposed labeling together with extensive information. See 21 U.S.C. § 360e(c) (1994) (App. 53a-54a); 21 C.F.R. § 814.20 (1995). First and foremost, the manufacturer must submit "full reports of all information" concerning investigations to determine the safety and effectiveness of the device, such as the results of the IDE investigation in this case. 21 U.S.C. § 360e(c)(1)(A) (1994) (App. 53a). In addition, the manufacturer must submit information concerning (i) the device's basic qualities, including its design, components, properties, and principles of operation, (ii) its production, including its manufacturing methods, processing, packaging, and installation, (iii) its performance standards, if any, and (iv) any other information requested by the FDA. See *id.* § 360e(c)(1)(B)-(D), (G) (1994) (App. 53a).

A PMA application is first referred to a panel of experts, 21 U.S.C. § 360e(c)(2) (1994) (App. 53a-54a), after which the FDA can either approve the device or request additional information or testing. *Id.* § 360e(d) (1994). Final approval can be granted only if the FDA finds there is a "reasonable assurance" that the device is "safe and effective," after "weighing any probable benefit to health from the device against any probable risk of illness or injury from such use." *Id.*

§ 360c(a)(2) (1994); 21 C.F.R. § 860.7 (1995). As this Court highlighted, "[d]espite its relatively innocuous phrasing, the process of establishing this 'reasonable assurance' . . . is a rigorous one." *Medtronic*, 64 U.S.L.W. at 4627 (Opinion of STEVENS, J.). Thereafter, the manufacturer must maintain detailed records and report to the FDA regarding the device. 21 U.S.C. § 360i (1994).

In short, both investigational devices approved through the IDE process, and Class III devices approved through the PMA process, are regulated by the FDA in virtually every respect--including their design, manufacture, labeling, distribution, and subsequent performance in actual use. For these reasons, both processes can only be viewed as constituting a "specific requirement" within the meaning of the FDA's own pre-emption regulations, 21 C.F.R. § 808.1(d) (1995), thereby implicating the full pre-emptive sweep of 21 U.S.C. § 360k(a) (1994). E.g., *Gile v. Optical Radiation Corp.*, 22 F.3d 540, 541 (3d Cir.), *cert. denied*, ___ U.S. ___, 115 S. Ct. 429, 130 L. Ed. 2d 342 (1994) (IDE process); *King v. Collagen Corp.*, 983 F.2d 1130, 1134 (1st Cir.), *cert. denied*, 510 U.S. 824, 114 S. Ct. 84, 126 L. Ed. 2d 52 (1993) (PMA process); *Stamps v. Collagen Corp.*, 984 F.2d 1416, 1422, n.3 (5th Cir.), *cert. denied*, 510 U.S. 824, 114 S. Ct. 86, 126 L. Ed. 2d 54 (1993) (PMA process); *Slater*, 961 F.2d at 1332 (IDE process).

Indeed, this case bears a striking resemblance to the hypothetical used by Justice Breyer to demonstrate that state tort laws can and do establish product requirements and therefore may be pre-empted by federal regulation. *Medtronic*, 64 U.S.L.W. at 4635 (BREYER, J., concurring in part and concurring in the judgment). Instead of involving the appropriate length for wires with hearing aids, this case involves the appropriate thickness of a particular component of a replacement knee joint. Here, the FDA had approved investigational use, and later general marketing, of this product with a 7 millimeter thickness (as well as with other thicknesses), but an Illinois trial court rejected that thickness, concluding that it left the product in an unreasonably dangerous and defective condition, based on the testimony of plaintiff's experts, who felt that a thickness of 9 millimeters was more appropriate for the component in question.

As Justice Breyer points out, an Illinois state agency could not issue a regulation requiring a minimum 9 millimeter thickness for this component. Yet "[t]he effects of the state agency regulation and the state tort suit are identical." *Medtronic*, 64 U.S.L.W. at 4635 (BREYER, J., concurring in part and concurring in the judgment). Upholding the damages award in this case--which is based on a state-law claim that the device is unreasonably dangerous--will have "the effect of establishing a substantive requirement for a specific device," 21 C.F.R. § 808.1(d) (1995), that plainly relates to its "safety and effectiveness." 21 U.S.C. § 360k(a)(2) (1994). Such an award could only be based on a finding that the device was *un*safe, *in*effective, or *un*fit for use, in which case the manufacturer would be forced either to alter its design and manufacturing processes or to be subject to liability despite the FDA's considered determinations--pursuant to its exclusive regulatory authority--that the device first showed sufficient promise of being proved safe and effective to justify the risk of its experimental use in human beings, and after clinical study, that the device has been demonstrated to be "safe and effective" and hence fit for general use. This would, as a practical matter, reflect "second guessing" of the FDA's expertise and experience with medical devices by lay jurors or a court. Congress surely did not intend to condone such a result when enacting § 360k(a) as part of its comprehensive regulatory scheme for the integrated IDE and PMA processes.

Manufacturers of innovative devices already confront formidable hurdles when attempting to successfully reach the market and recoup their investment in critical life-saving or life-enhancing technology. For those who already have to first comply with the clinical investigation requirements of the IDE process following invention of the device, and thereafter satisfy the grueling PMA process and maintain a continuous reporting relationship with the FDA, adding a second level of random-order scrutiny of their devices--with all the vagaries of conflicting state laws and procedural rules as well as jury verdicts--can only add to the uncertainties they face, with the very real prospect of discouraging innovation.

C. The Important Federal Question Presented

The Illinois Supreme Court held that the FDA's exclusive domain over medical devices did not reflect a choice by Congress to vest that agency with sole authority to address issues involving their safety and effectiveness (App. 10a-11a). But as *Medtronic* makes clear, when the FDA formally approves the investigative use of a device to determine its ultimate safety and effectiveness by the IDE process, or the general marketing of a device pursuant to the PMA process, thereby establishing "specific requirements" for that device, § 360k(a) divests states of any authority to impose "additional" or "differing" requirements with regard to the design, manufacture, labeling, or use of the device, whether by statute, regulation, or damages awards based on findings that the device is unreasonably dangerous or unfit for use.

This Petition asks the Court to determine whether, in light of its holding in *Medtronic*, MDA pre-emption for IDE-approved and PMA-approved devices is jurisdictional in nature and thus deprives state courts of the ability to review the safety and efficacy of devices that have already been determined suitable for investigative use or completed the most rigorous FDA review. Only by recognizing the jurisdictional nature of the pre-emption accorded IDE-approved and PMA-approved devices can the FDA's exclusive authority be properly effectuated consistent with the intentions of Congress.

CONCLUSION

For all the foregoing reasons, this Court should grant certiorari in this case and reverse the holding of the Illinois Supreme Court. At a minimum, this Court should vacate and remand this case for consideration in light of *Medtronic*.

Respectfully submitted,

Steven C. Kany
Louis B. Bernstein
PFIZER INC.
235 E. 42nd Street
New York, NY 10017
(212) 573-2323

James V. O'Brien
Thomas L. Caradonna
LEWIS, RICE &
FINGERSH, L.C.
500 N. Broadway, Ste. 2000
St. Louis, MO 63102
(314) 444-7600

Barry Levenstam
Counsel of Record
Stephanie A. Scharf
Matthew M. Neumeier
JENNER & BLOCK
One IBM Plaza
Chicago, IL 60611
(312) 222-9350

Counsel for Petitioner

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